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Gould v. Quigg (CA FC) 3 USPQ2d 1302 (6/25/1987)

Gould v. Quigg (CA FC) 3 USPQ2d 1302

## Gould v. Quigg

### U.S. Court of Appeals Federal Circuit 3 USPQ2d 1302

Decided June 25, 1987  
No. 86-1274

#### Headnotes

## PATENTS

### 1. Patentability/Validity — Adequacy of disclosure [Enablement] (§ 115.11)

Federal district court did not err, in reversing finding by patent examiner and by Board of Patent Appeals and Interferences that patentee had presented no evidence to overcome prima facie case of lack of enablement, by accepting testimony of expert who, in determining his opinion as to whether disclosure was enabling at time of application's filing date, relied upon technical article that was published after filing date.

### 2. Patentability/Validity — In general (§ 115.01)

Federal district court lacks authority, in action under 35 USC 145 to set aside decision of Board of Patent Appeals and Interferences affirming examiner's rejection of claims, to direct issuance of patent, but rather court should authorize Commissioner of Patents and Trademarks "to issue such patent on compliance with the requirements of law."

## Case History and Disposition:

Appeal from District Court for the District of Columbia, Flannery, J.; 229 USPQ 1.

Action by Gordon Gould against Donald J. Quigg, Commissioner of Patents and Trademarks, under 35 USC 145. From decision directing Commissioner to issue patent, Commissioner appeals. Affirmed in part, vacated in part, and remanded.

**Attorneys:**

Fred E. McKelvey, deputy solicitor (Joseph F. Nakamura, solicitor, with him on brief), for appellant.

Roy H. Wepner of Lerner, David, Littenberg, Krumholz & Mentlik, both of Westfield, N.J., and R. V. Lupo of Lupo, Lipman & Lever, both of Washington, D.C. (Sidney David, William L. Mentlik, and Lerner, David, Littenberg, Krumholz & Mentlik, all of Westfield, N.J., with them on brief), for appellee.

**Judge:**

Before Bennett, Senior Circuit Judge, and Bissell and Archer, Circuit Judges.

**Opinion Text**

**Opinion By:**

Bissell, Circuit Judge.

5/823 6/11 USP 4,704,583

This is an appeal from the judgment of the United States District Court for the District of Columbia directing the Commissioner of Patents and Trademarks to issue a patent containing claims 1-15 of U.S. Application No. 823,611 (T611) filed August 11, 1977, "insofar as they relate to a gas discharge amplifier." *Gould v. Mossinghoff*, 229 USPQ 1, 14 (D.D.C. 1985). We affirm-in-part, vacate-in-part, and remand.

**BACKGROUND**

The application in suit arrives at this court after a long, arduous journey through the patent continuation, division, and interference practices in the U.S. Patent and Trademark Office (PTO), starting with an application filed on April 6, 1959, U.S. Application No. 804,540 (T540). See 35 U.S.C. §§ 120, 121, and 135. While the T540 application disclosed many inventions in laser technology, the T611 application relates only to gas discharge light amplifiers that employ atomic and subatomic particle collisions in gases to amplify light by stimulated emission of radiation. 1

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During prosecution of the T611 application the PTO rejected the claims under 35 U.S.C. § 112 since the T540 application failed to meet the disclosure and enablement requirements of this section of the statute. Upon Gould's appeal to the Patent and Trademark Office Board of Patent Appeals and Interferences (Board), the Board affirmed those rejections by the examiner. Gould instituted a civil action on August 11, 1977, under 35 U.S.C. § 145 (1976) seeking an order from the district court authorizing the Commissioner of Patents and Trademarks to issue to Gould a patent based on his application.

In light of new evidence presented in the district court proceeding, the district court found that "the decisions by the examiner and the Board were incorrect." 229 USPQ at 9 (FF 87). 2 The district court found that "[t]he examiner had no evidentiary basis to question the adequacy of Gould's disclosure, and Gould's disclosure should have been accepted as presumptively enabling." *Id.* at 9-10 (FF 86). Furthermore, the district court went on to conclude that the specification of Gould's patent application contained "a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." *Id.* at 11, 13 (FF 94, CL 4). The district court then *directed* the Commissioner to issue to Gould a patent including claims 1 through 15 as set forth in the application. *Id.* at 14 (FJ 3). General familiarity with the district court's findings of fact and conclusions of law is presumed.

## ISSUES

The Commissioner raises the following issues in this appeal:

1. Whether the district court erred in concluding that the examiner and the Board lacked a reasonable basis for doubting the enablement in Gould's application.
2. Whether the district court erred, as a matter of law, in crediting certain testimony upon which it based its conclusion that the T540 application contained an enabling disclosure for a gas discharge light amplifier, *i.e.*, whether the T540 application enabled one skilled in the art to achieve a population inversion in the amplifying system.
3. Whether the district court erred, as a matter of law, in *directing* as opposed to *authorizing* the Commissioner to issue a patent.

## OPINION

"An applicant dissatisfied with the decision of the Board of Patent Appeals and Interferences in an appeal under section 134 . . . may . . . have remedy by civil action against the Commissioner in the United States District Court for the District of Columbia. . . . The court may adjudge that such applicant is entitled to receive a patent for his invention, as specified in any of his claims involved in the decision of the Board of Patent Appeals and Interferences . . . and such adjudication shall authorize the Commissioner to issue such patent on compliance with the requirements of law." 35 U.S.C. § 145 (1982 & Supp. Ill 1985). While the evidentiary record before the Board serves as the "evidentiary nucleus" of the district court proceeding in a section 145 action, the parties are entitled to submit additional evidence. *Fregeau v. Mossinghoff*, 776 F.2d 1034, 1037, 227 USPQ 848, 850 (Fed. Cir. 1985); *see also Hoover Co. v. Coe*, 325 U.S. 79, 83 [ 65 USPQ 180, 183] (1945) ("[In an action under 35 U.S.C. § 63, the predecessor to section 145,] a formal trial is afforded on proof which may include evidence not presented in the Patent Office." [Footnote omitted.]). Furthermore, in such an action, the district court can set aside the Board's fact findings only if they are clearly erroneous, but if new evidence is presented on a disputed question of fact, a *de novo* fact finding is made by the district court. *Fregeau*, 776 F.2d at 1038, 227 USPQ at 851; *see also Morgan v. Daniels*, 153 U.S. 120, 125 (1894) ("the decision [in the Patent Office] must be accepted as controlling upon [a] question of fact in any subsequent suit between the same parties, unless the contrary is established by testimony which in character and amount carries thorough conviction").

Enablement under 35 U.S.C. § 112, first paragraph, is a question of law. *See, e.g., Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960 n.6, 220 USPQ 592, 599 n.6 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 [ 225 USPQ 232 ] (1984). However, in this case, extensive additional evidence directed not to the ultimate legal question of enablement, but to its numerous factual underpinnings

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was presented to the district court. Accordingly we review the district court's judgment in this case, as we would any bench trial, for clearly erroneous findings of fact and errors of law. *Fregeau*, 776 F.2d at 1037, 227 USPQ at 851; *see Fed. R. Civ. P. 52(a); Atlas Powder Co. v. E. I. Dupont de Nemours & Co.*, 750 F.2d 1569, 1573, 224 USPQ 409, 411 (Fed. Cir. 1984) (appellant must establish that the district court's legal conclusions were erroneous, or that the underlying findings were clearly erroneous); *see also Anderson v. City of Bessemer City, North Carolina*, 470 U.S. 564, 573 (1985).

## I

The gist of the Commissioner's contention on appeal is that the Board's affirmance of the examiner's rejection of the T611 application should be affirmed because the examiner had a reasonable basis for doubting the enablement of Gould's T540 application and Gould presented no evidence either before the Board or the district court to rebut this *prima facie* case of lack of enablement. Even if the Commissioner is correct in his contention that the examiner presented before the Board a *prima facie* case of lack of enablement and that the district court erred when it held to the contrary, an automatic reversal of the judgment of the district court does not follow. Since the Commissioner does not prevail on his contention that Gould presented no evidence before the district court to overcome the asserted *prima facie* case of lack of enablement, we need not, and do not, address the issue of whether the examiner had a reasonable basis for doubting the enablement of the T540 application.

## II

The Commissioner contends that, as a matter of law, the district court erred in relying on a post-1959 expert opinion (Dr. Franken's testimony) based upon two rationales when (a) one rationale (a post-1959 technical article) is irrelevant as a matter of law, and (b) the other rationale (a post-1959 laser device) was found insufficient by the district court.

Dr. Franken, Gould's expert, testified that the disclosure in the T540 application, when considered in conjunction with the state of the art as it existed as of the application's April 6, 1959, filing date, was sufficient to enable one of ordinary skill to build, without undue experimentation, a sodium-mercury light amplifier. As its initial argument, the Commissioner would have this court hold that the district court should have totally disregarded Dr. Franken's testimony because his opinions concerning the state of the art in 1959 were not based upon his having personally built a laser circa 1959. In addition, since the trial took place some 26 years after Gould's filing date, Dr. Franken's opinion was based essentially upon knowledge acquired by him during the intervening years between 1959 and 1985.

The Commissioner points to competing expert testimony to support the Board's decision. While the experts did hold different opinions, the district court specifically commented on Dr. Franken's credibility, stating:

The court accords more weight to the testimony of Dr. Franken than to the testimony of Dr. Feldman. Both experts are highly qualified, but in the court's opinion, Dr. Franken's credentials and more impressive. His manner of testifying and the reasons given for his opinions have convinced the court as the factfinder to accept his expert testimony over the conflicting expert testimony of Dr. Feldman.

226 USPQ at 10 (FF 93).

The district court was fully aware of the 26-year time interval between Gould's filing date and the trial and must be presumed to have considered it in finding the facts. Perhaps one reason the district court credited Dr. Franken's testimony over that of Dr. Feldman is that Dr. Franken was a person skilled in the relevant art at the time of Gould's filing date. *Id.* at 2 (FF 6-7). In any event, as stated in *Gyromat Corp. v. Champion Spark Plug Co.*, 735 F.2d 549, 552, 222 USPQ 4, 6 (Fed. Cir. 1984), "[t]he credibility of the witnesses and the weight to be given to their testimony and the other evidence in the record, however, is a matter for the trier of the facts." See also *Anderson*, 470 U.S. 564.

In attempting to discount the testimony of Dr. Franken, the Commissioner argues that as of Gould's filing date, no person had built a light amplifier or measured a population inversion in a gas discharge. "The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it." *In re Chilowsky*, 29 F.2d 457, 461, 108 USPQ 321, 325 (CCPA 1956); see also *In re Ferens*, 417 F.2d 1072, 1074, 163 USPQ 609, 611 (CCPA 1969).

The Commissioner argues that Dr. Franken's testimony is worthless, because the foundation for his expert opinion was based solely upon his reliance on (1) a technical article published after Gould's filing date

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and (2) a laser device built after the filing date, both of which the Commissioner contends must be disregarded. This argument as to the worthlessness as a whole of Dr. Franken's testimony is without merit.

[1] As to the technical article, it is true that a later dated publication cannot supplement an insufficient disclosure in a prior dated application to render it enabling. In this case, the later dated publication was not offered as evidence for this purpose. Rather, it was offered as evidence of the level of ordinary skill in the art at the time of the application and as evidence that the disclosed device would have been operative. Compare *In re Hogan*, 559 F.2d 595, 605, 194 USPQ 527, 537 (CCPA 1977) ("This court has approved use of later publications as evidence of the state of the art *existing on the filing date* of an application." (footnotes omitted) (emphasis in original)) with *In re Glass*, 492 F.2d 1228, 1232, 181 USPQ 31, 34 (CCPA 1974) (later publications which add to the knowledge of the art cannot be used to supplement an insufficient disclosure); cf. *Hirschfield v. Banner*, 462 F.Supp. 135, 142, 200 USPQ 276, 281 (D.D.C. 1978), aff'd, 615 F.2d 1368 (D.C. Cir. 1980), cert. denied, 450 U.S. 994 [ 210 USPQ 776 ] (1981) ("factual evidence directed to the amount of time and effort and level of knowledge required for practice of the invention from the disclosure alone . . . can be expected to rebut a *prima facie* case of nonenablement"); *In re Pottier*, 376 F.2d 328, 330 n.1, 153 USPQ 407, 408 n.1 (CCPA 1967) ("[W]hether or not an invention would be deemed operative by one of ordinary skill in the art is determined, not at the time the invention was made but rather (at the earliest) at the time of the examiner's call for proof."). It was not legal error for the district court to accept the testimony of an expert who had considered a later publication in the formulation of his opinion as to whether the disclosure was enabling as of the time of the filing date of the T540 application.

There is no disagreement between the district court and the Commissioner that the laser device built after the filing date does not duplicate the amplifier disclosed by Gould in 1959 and that the construction of the device had doubtful probative value. The district court concluded that "[the evidence regarding the Optelecom device] does not prove by a preponderance of the evidence either that Gould's disclosure is enabling or that sodium and mercury without argon will work." *Id.* at 10 (FF 95). The finding that one piece of evidence, offered by the prevailing party, is not probative, does not require reversal of the district court's conclusion on enablement. Dr. Franken gave underlying reasons to support his opinion "[q]uite apart from [his] consideration of the [post-1959 technical article] and apart from the [post-1959 laser device]" that Gould's specification was enabling to one of ordinary skill in the art. Appendix at 205.

Thus, regardless of whether the examiner was correct in questioning enablement during prosecution, once a full trial on the issue occurred that flushed out the actual state of the art and level of experimentation, the district court reached a distinct and more informed conclusion on enablement. We find no legal error in the district court's reliance on Dr. Franken's testimony to support its conclusion of enablement.

### III

[2] Turning now to the issue of whether the district court has authority to direct the issuance of a patent, we conclude it does not. An action under 35 U.S.C. § 145 is in essence an action to set aside a decision of the Board and to resolve questions of patentability to the extent issues are raised at trial. *See Hoover Co. v. Coe*, 325 U.S. 79, 85 [ 65 USPQ 180, 183] (1945) (The issue was whether the district court had jurisdiction to review a final rejection of a claim for the purposes of provoking a subsequent interference.); *Fregeau*, 776 F.2d at 1037, 227 USPQ at 851 ("[I]t cannot seriously be contended that a § 145 action is other than one to overturn the board's decision."). It matters not that additional evidence is permitted in a civil action under section 145, allowing the district court to make *de novo* fact findings. *See In re Fisher*, 448 F.2d 1406, 1407, 171 USPQ 292, 293 (CCPA 1971) ("As we have often pointed out, we pass only on rejections actually made and do not decree the issuance of patents."). We presume that the Commissioner will follow a proper order issued by the district court and perform the duties imposed upon the PTO by statute. *See Hoover*, 325 U.S. at 88 [ 65 USPQ 184].

### CONCLUSION

Since the Commissioner has not convinced this court that any finding of fact is clearly erroneous, or that there are errors of law, that portion of the district court's judgment setting aside the Board's decision is affirmed. However, since the district court's order directed the Commissioner to issue a patent for the T611 application, we vacate the

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order to the extent that it so *directs* and remand for issuance of an order that "shall authorize the Commissioner to issue such patent on compliance with the requirements of law." 35 U.S.C. § 145 (1982 & Supp. III 1985).

**AFFIRMED-IN-PART, VACATED-IN-PART, AND REMANDED**

### Footnotes

Footnote 1. A more detailed treatment of the technology can be found in prior decisions related to this application. *Gould v. Mossinghoff*, 215 USPQ 310 (D.D.C. 1982), *rev'd*, 711 F.2d 396, 219 USPQ 383 (D.C. Cir. 1983), *on remand*, 229 USPQ 1 (D.D.C. 1985). Court decisions involving patent applications containing essentially the same disclosure as the T611 application, but claiming different inventions and involving different issues have been numerous. See *Gould v. Control Laser Corp.*, 705 F.2d 1340, 217 USPQ 985 (Fed. Cir.), *cert. denied*, 464 U.S. 935 [ 220 USPQ 385 ] (1983); *In re Gould*, 673 F.2d 1385, 213 USPQ 628 (CCPA 1982); *Gould v. Hellwarth*, 472 F.2d 1383, 176 USPQ 515 (CCPA 1973); *Gould v. Schawlow*, 363 F.2d 908, 150 USPQ 634 (CCPA 1966); *Patlex Corp. v. Mossinghoff*, 585 F.Supp. 713 [ 220 USPQ 342 ] (E.D. Pa. 1983); *aff'd in part and vacated in part*, 758 F.2d 594, 225 USPQ 243 (Fed. Cir.), *reh'g granted in part*, 771 F.2d 480, 226 USPQ 985 (Fed. Cir. 1985).

Footnote 2. FF \_\_\_ represents Finding of Fact; CL \_\_\_ represents Conclusion of Law; FJ \_\_\_ represents Final Judgment.

- End of Case -

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**Treatment of High-Risk Angioplasty Patients with 7E3, a  
Chimeric Monoclonal Fab Antibody That Blocks the Integrin  
IIb/IIIa Receptor on Platelets**

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Dr. James N. Woody, Senior Vice President, Research &  
Development and Chief Scientific Officer, Centocor, Inc.



Treatment of High Risk Angioplasty Patients  
with 7E3, a Chimeric Monoclonal Fab Antibody  
that Blocks the Integrin IIb/IIIa Receptor on Platelets

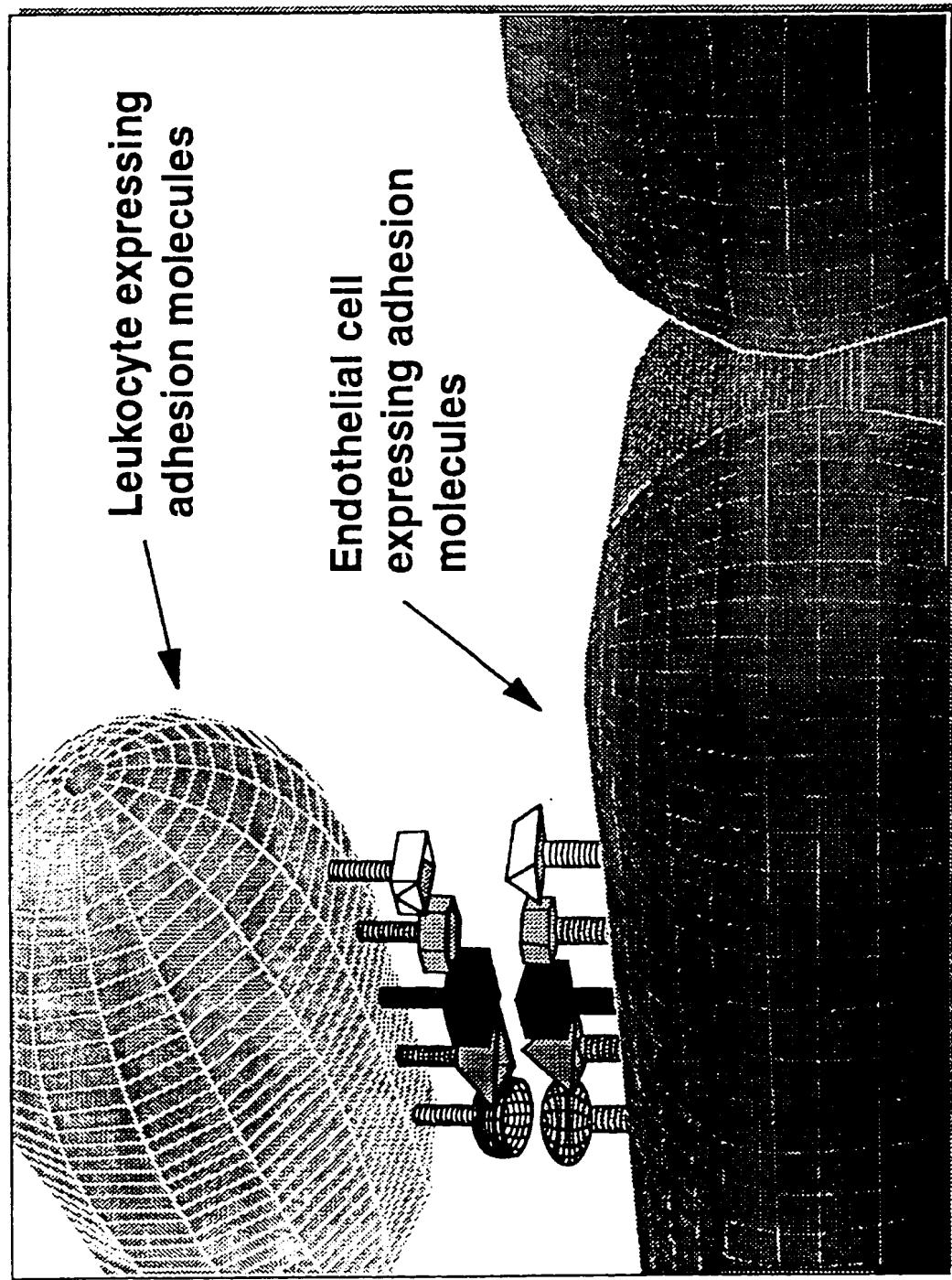
Cambridge HealthTech Institute  
Commercial Prospects of  
**CELL ADHESION MOLECULES**

December 6-8, 1993  
San Diego, California

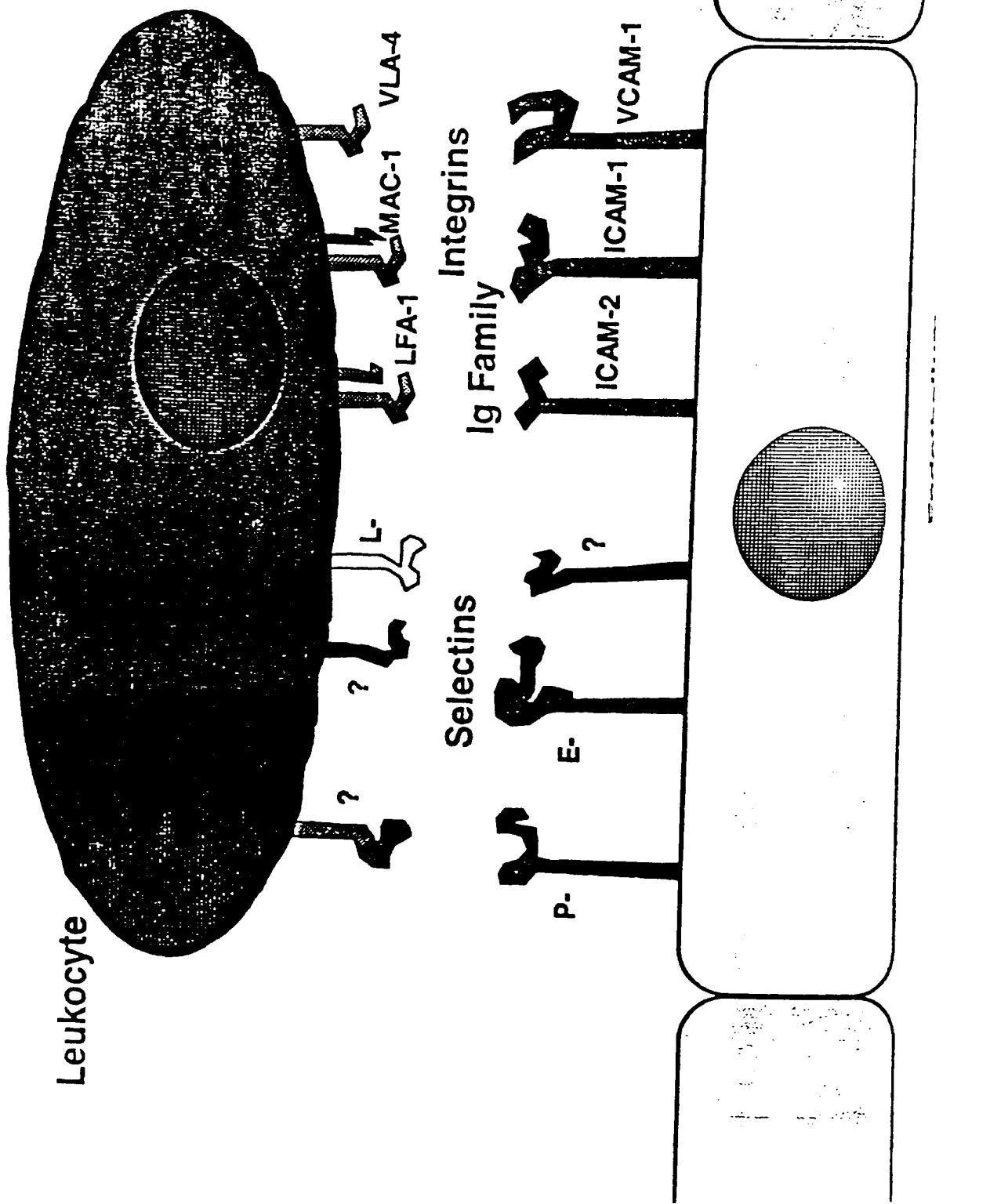
CENTOCOR

ADHESION MOLECULE PROGRAM

# Leukocyte Adhesion to Endothelial Cells From the Bottom Up



# Leukocyte-Endothelial Adhesion Molecules



**ADHESION MOLECULES**  
(mononuclear cells, endothelial cells, etc.)

**Integrins:**      **B<sub>1</sub>** (VLA-4)  
                        **B<sub>2</sub>** (CD11/18 - LFA-1, MAC-1, etc.)

**L-Selectins:**      **MEL 14**, **LAM-1**  
                        LECAM-1

**P-Selectins:**      **GMP-140**  
                        PADGEM, CD62

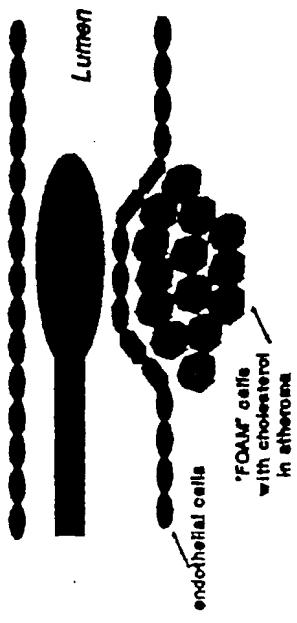
**E. Selectins:**      **ELAM-1**

## PLATELET INTEGRINS AND LIGANDS

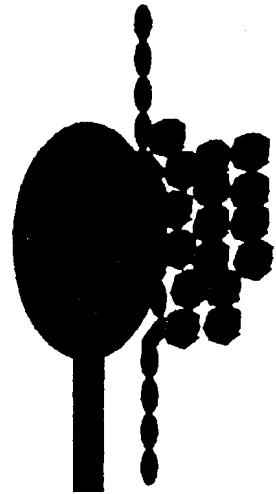
Platelet Receptor	Ligand
GPIIa/IIa ( $\alpha_2B_1$ )	Collagen
GPIC/IIIa ( $\alpha_5B^1$ )	Fibronectin
GPIIb/IIIa ( $\alpha II_bB_3$ )	Fibrinogen, Fibronectin Ron Willebrand factor Vitronectin
- $\alpha_6B_1$	Laminin
- $\alpha_5B_3$	Vitronectin, Fibrinogen

## BALLOON ANGIOPLASTY PROCEDURE (PTCA)

ANGIOPLASTY BALLOON OVER  
ATHEROMA (PLAQUE) SITE



EXPANDED BALLOON COMPRESSING  
ATHEROMA



# POST ANGIOPLASTY CLOT FORMATION AND EMBOLIZATION PREVENTED BY 7E3

PLATELET - FIBRIN CLOT AT  
ANGIOPLASTY SITE



CENTORX (7E3) BLOCKS PLATELET  
AGGREGATION PREVENTING ACUTE  
REOCCCLUSION AND EMBOLI

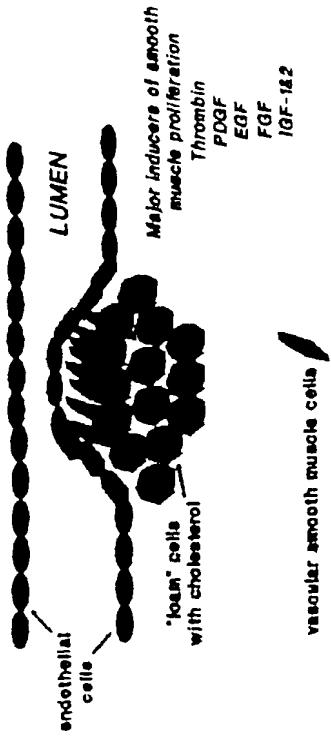
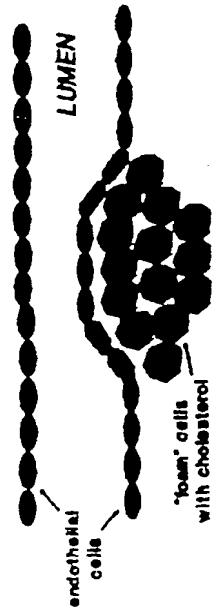


platelets fibrin  
Centorx (7E3)  
chimeric Fab antibody

# RESTENOSIS AFTER ANGIOPLASTY

CORONARY RESTENOSIS FOLLOWING  
ANGIOPLASTY IN 30-40% OF PATIENTS  
AT 6 MONTHS

ATHEROMA BEGINNING TO  
OCCLUDE A CORONARY ARTERY

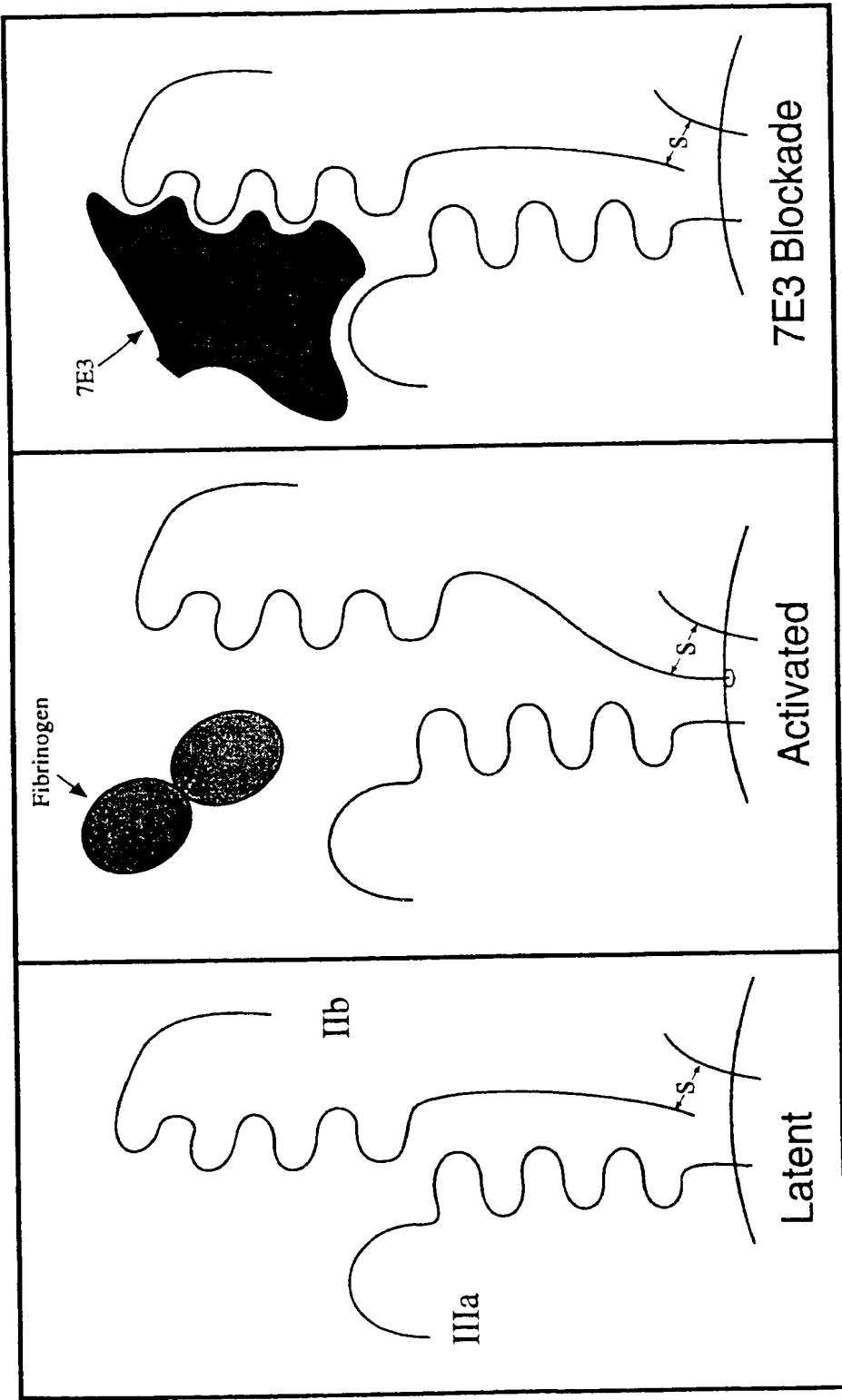


## **PLATELET ADHESION AND AGGREGATION**

**Adhesion - all integrins plus none integrins**

**Aggregation - IIb/IIIa**

# Schematic of IIb/IIIa Receptor With Blockade by 7E3 Fab



## **EPIC TRIAL**

- 2100 patients undergoing "high risk" PTCA
- Randomized to:
  - Placebo
  - Bolus 7E3 (single dose)
  - Bolus 7E3 + 12 hr infusion
- Endpoints - occurrence within 30 days
  - Death
  - Acute MI (Q wave, other)
  - Need for urgent (re) PTCA
  - Emergency CABG procedure
  - STENT placement
  - Balloon pump placement

## **RESULTS - PRIMARY ENDPOINTS**

**Placebo**            **12.8%**

**Bolus**            **11.5%**

**Bolus + Infusion**    **8.3%**

**Dose response p=0.009**

**Placebo vs. Bolus + Infusion  
(34.8% reduction, p=0.008)**

## SAFETY CONSIDERATIONS (%)

	Placebo <u>(n=680)</u>	Bolus <u>(n=689)</u>	Bolus+Infusion <u>(n=701)</u>
Death	1.8	1.3	1.3
Stroke	2.2	1.8	1.6
Major Bleed*	7	11	14
Minor Bleed**	10	15	17
Transfusions			
Red cells	7	13	15
Platelets	3	4	6

\* occurred during CABG, or at site of vascular puncture

\*\* most at vascular puncture site

## SUMMARY AND CONCLUSIONS

- Blockade of IIb/IIIa receptors using 7E3-Fab reduces platelet aggregation
- 7E3 administration significantly reduces acute events in patients with active thrombotic lesions
  - Unstable angina
  - AMI
  - High risk architecture
- Platelet blockade is associated with a small increased bleeding risk
- Follow-up of patients receiving 7E3 at 6 months in the EPIC trial showed continued benefit in terms of reduction of clinical restenosis ( $p=0.009$ )